IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kazuhiko NAKADA et al. Art Unit: 1614

Serial Number: 10/088,770 Examiner: Zohreh A. Fay

Filed: March 20, 2002

For: LIQUID PREPARATION FOR CONTACT LENSES

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Kazuhiko Nakada residing at c/o Menicon Co., Ltd., Central Research Laboratories, 1-10, Takamoridai 5-chome, Kasugai-shi, Aichi-ken, Japan, duly declare and say as follows:

1. I graduated from Department of Chemical Engineering, Faculty of Engineering, Nagoya University, Nagoya, Japan, in the year 1979.

2. I have been employed since 1979 by Menicon Co., Ltd.

3. Since 1979 I have been engaged in research and development on contact lenses and liquid preparations for contact lenses.

4. I am one of the named joint inventors of the above-identified patent application, and I have read and am familiar with the above-identified patent application and the Office Action thereto mailed September 24, 2003.

5. I made experiments in order to show that polyamines

prepared using allylamine or vinylamine have a high antimicrobial activity, and that the polyamines exhibit an excellent antimicrobial or antiseptic effect at a very low concentration and provide liquid preparations having a high safety to the eyes which are suitable for cleaning, rinsing, disinfecting and preserving contact lenses.

6. Experiments were made as follows:

Examples 1 and 2 and Comparative Examples 1 to 3

Liquid preparations were prepared by dissolving polyallylamine having a weight average molecular weight of about 10,000 in water in concentrations shown in Table 1.

The disinfecting test of the obtained liquid preparations was made according to United States Pharmacopoeia 23 using Candida albicans IFO 1594 and Pseudomonas aeruginosa IFO 13275 as test microorganisms. The results are shown in Table 1, wherein the values denote Log reduction of the number of viable cells of the microorganism which were inoculated and allowed to stand at room temperature for 4 hours.

Comparative Example 4

The above procedure was repeated except that 1 ppm of polyhexamethylene biguanide (PHMB) was used as an antibacterial agent instead of polyallylamine. The results are shown in Table 1.

Table 1

	Concentration of polyallylamine (w/v %)	Log reduction	
		Pseudomonas aeruginosa	Candida albicans
Com. Ex. 1	0.12 (=1,200 ppm)	>3.04	4.16
Com. Ex. 2	0.012 (=120 ppm)	>3.04	3.86
Example 1	0.0012 (=12 ppm)	>3.57	>3.87
Example 2	0.00012 (= 1.2 ppm)	>3.57	1.18
Com. Ex. 3	0.000012 (=0.12 ppm)	-0.95	-0.04
Com. Ex. 4	PHMB (1 ppm)	-	0.46

PHMB: polyhexamethylene biguanide

7. It is observed in Table 1 that polyallylamine has a high antimicrobial activity.

It is also observed that the liquid preparation of Example 1 has an antimicrobial effect on the same level as that of Comparative Examples 1 and 2 which contain polyallylamine in a concentration of 10 times or 100 times. It would be readily understood that the liquid preparations of Examples 1 and 2 have a high antimicrobial effect and, moreover, are highly safe for the eyes.

Further, it is observed in Table 1 that the liquid preparation of Comparative Example 4 which contains a conventionally used antibacterial agent, i.e., polyhexamethylene biguanide, in a concentration as low as 1 ppm, does not exhibit a sufficient antimicrobial effect.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

This 4th day of December, 2003

by Kazuhiko Nakada

Kazuhiko Nakada

We, the undersigned witnesses, hereby acknowledge that Kazuhiko Nakada is personally known to us and did execute the foregoing Declaration in our presence on:

Date: December 4, 2003 Witness Kazuhiro Kotou

Date: December 4, 2003 Witness Rika Ozeki